

**United States Court of Appeals
for the Federal Circuit**

2014-1294

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., and
RHODES TECHNOLOGIES,

Plaintiffs-Appellants,

v.

EPIC PHARMA, LLC,

Defendant-Appellee.

Appeal from the United States District Court for the Southern District of New
York in No. 1:13-cv-00683-SHS, Judge Sidney H. Stein.

2014-1296

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., and
RHODES TECHNOLOGIES,

Plaintiffs-Appellants,

v.

MYLAN PHARMACEUTICALS INC., and
MYLAN INC.,

Defendants-Appellees.

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-02959-SHS, Judge Sidney H. Stein.

2014-1306, -1307

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P.,
RHODES TECHNOLOGIES, and
GRÜNENTHAL GMBH,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant-Appellee.

Appeals from the United States District Court for the Southern District of New York in No. 1:11-cv-08153-SHS, Judge Sidney H. Stein.

2014-1311, -1312, -1313, -1314

GRÜNENTHAL GMBH,
PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., and
RHODES TECHNOLOGIES,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

Appeals from the United States District Court for the Southern District of New York in Nos. 1:11-cv-02037-SHS and 1:12-cv-05083-SHS, Judge Sidney H. Stein.

**APPELLEES' OPPOSED MOTION TO FILE SEPARATE
RESPONSE BRIEFS**

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Amneal Pharmaceuticals, LLC*

FORM 9. Certificate of Interest**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**Purdue Pharma L.P. v. Amneal Pharmaceuticals, LLCNo. 14-1306, -1307**CERTIFICATE OF INTEREST**Counsel for the (petitioner) (appellant) (respondent) **appellee** (amicus) (name of party)Amneal Pharmaceuticals, LLC certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Amneal Pharmaceuticals, LLC

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Amneal Pharmaceuticals, LLC

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Defendant Amneal Pharmaceuticals, LLC ("Amneal") certifies that Amneal has two parent corporations, Amneal Holdings, LLC, and Amneal Pharmaceuticals Holding Company, LLC and that no publicly held company owns 10 percent or more of Amneal's stock.4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:AKIN GUMP STRAUSS HAUER & FELD LLP: Barbara L. Mullin, Steven D. Maslowski, Angela Verrecchio, Matthew A. Pearson, Jason E. Weil, Karen R. Poppel (now with NOVAK DRUCE CONNOLLY BOVE & QUIGG), Neil Duchez (now with MAYER BROWN); BUDD LARNER PC: Stuart D. Sender, Kenneth E. Crowell.November 3, 2014

Date

/s/ Barbara L. Mullin

Signature of counsel

Barbara L. Mullin

Printed name of counsel

Please Note: All questions must be answered

cc: _____

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Grunenthal Gmbh, Purdue Pharma L.P., The P.F.

Laboratories, Inc., Purdue Pharmaceuticals L.P., and

Rhodes Technologies

v. Teva Pharmaceuticals USA, Inc.

No. 14-1311; 14-1312; 14-1313; 14-1314

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Teva Pharmaceuticals USA, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Teva Pharmaceuticals USA, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Teva Pharmaceuticals USA, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

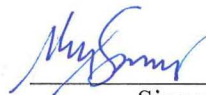
Teva Pharmaceuticals USA, Inc. is owned 100% by Orvet UK Unlimited, which in turn is owned 100% by Teva Pharmaceuticals Europe B.V., which in turn is owned 100% by Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly-traded company in the ownership of chain of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus nowrepresented by me in the trial court or agency or are expected to appear in this court are:

CARLSON, CASPERS, VANDENBURGH, LINDQUIST & SCHUMAN PA: Mark D. Schuman, Jeffer Ali, Todd S. Werner, Samuel L. Lockner, Sarah M. Stensland, Jennell C. Bilek, Alex J. Olson; AKIN GUMP STRAUSS HAUER & FELD LLP: Barbara L. Mullin, Steven D. Maslowski, Angela Verrecchio, Matthew A. Pearson, Jason Weil; NOVAK DRUCE CONNOLLY BOVE & QUIGG: Karen R. Poppel; MAYER BROWN: Neil DuChez

3-11-14

Date



Signature of counsel

Mark D. Schuman

Printed name of counsel

Please Note: All questions must be answered

cc: _____

INTRODUCTION

Pursuant to Federal Circuit Rule 28(c) and Federal Rule of Appellate Procedure 2, Appellees Teva Pharmaceuticals USA, Inc. (“Teva”), and Amneal Pharmaceuticals, LLC (“Amneal”) respectfully move this Court to allow each of these Appellees to file a response brief. One brief, by Teva, would respond to the opening brief filed by Appellant Grünenthal GmbH (“Grünenthal”). The second brief, by Amneal, would respond to the opening brief filed by Appellants Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively “Purdue”). If separate briefs are not permitted, then Teva and Amneal respectfully move to expand the length of a single responsive brief to a limit of 21,000 words.

Pursuant to Federal Circuit Rule 27(a)(5), Defendants-Appellees Teva and Amneal have discussed this motion with Plaintiffs-Appellants Grünenthal and Purdue and they have indicated that they oppose the present motion and plan to file a response.

SUMMARY OF REASON FOR THE REQUEST

Grünenthal is the assignee of one patent at issue on appeal. That patent, very generally, is directed to an abuse-deterrent formulation of a drug. On October 6, 2014, Grünenthal filed its opening brief directed solely to that abuse-deterrent

formulation patent. Although Grünenthal has asserted that patent against Appellee Teva, Grünenthal has never asserted that patent against Appellee Amneal.

Purdue is the assignee of the remaining three patents at issue in this appeal. Those patents are directed to an active pharmaceutical ingredient having certain properties. On October 6, 2014, Purdue filed its opening brief directed almost entirely to these active compound patents. Purdue asserted those patents against both Teva and Amneal.

Teva and Amneal agree with Appellants that it is appropriate to separate the issues on appeal relating to the Grünenthal patent from those relating to the Purdue patents. Indeed, because the witnesses, documents and evidence relating to these separate patent families do not overlap, the trial was conducted from opening statement through the close of evidence, first, on the Grünenthal patent. Then, the Purdue patents were tried, separately, from opening statement through the close of evidence.

Because the issues pertaining to each patent family are discrete and not asserted uniformly against the Appellees, Teva and Amneal request an Order permitting them to organize their briefs, as Appellants Grünenthal and Purdue have done, to address each patent family separately. Appellees are aware of the Practice Note to Federal Circuit Rule 28 as it relates to briefs filed by multiple parties represented by counsel from the same firm. Although attorneys from Akin Gump

Strauss Hauer & Feld LLP (“Akin Gump”) are identified as counsel of record for Teva and Amneal, at trial and throughout these proceedings, Akin Gump has defended Teva and Amneal only with respect to the Purdue patents. Teva had separate counsel who defended it in connection with the Grünenthal patent claims. Amneal was not sued under the Grünenthal patent at issue on appeal.

If the request for permission to file two separate briefs is not granted, then, in the alternative, Teva and Amneal respectfully move to expand the word count allowed in a single response brief to a limit of 21,000 words.

THE PERTINENT FACTS

This appeal involves four patents that fall into two distinct patent families.

A. The Grünenthal Patent

The Grünenthal patent at issue on appeal covers an opioid product having a high breaking strength designed to deter drug abuse (the “abuse deterrent” patent). Although Grünenthal has asserted several patents in this family, U.S. Patent No. 8,114,383 (the “383 patent”) is the only patent from the abuse-deterrent family that is at issue in this appeal. The 383 abuse-deterrent patent is assigned to Grünenthal GmbH and licensed to Purdue.

B. The Purdue Patents

The second patent family at issue on appeal covers processes for making oxycodone hydrochloride salt with a low level of certain α , β -unsaturated ketones

(“ABUKs”), and compositions of hydrochloride salt containing low levels of ABUKs. The three patents in this family—U.S. Patents No. 7,683,072 (the “072 patent”), No. 7,674,799 (the “799 patent”), and No. 7,674,800 (the “800 patent”) (collectively the “low-ABUK” patents)—are all related to each other. Each is a continuation of the same application, they have the same inventors, and they are all on their face assigned to the same assignee, Purdue Pharma L.P.

The low-ABUK patents and the abuse-deterrent patent do not have any overlapping inventors, do not share a specification, are not in the same family, and are not assigned to the same entity.

C. Purdue’s and Grünenthal’s Case Against Teva

First, on March 23, 2011, Purdue and Grünenthal filed suit against Teva alleging infringement of the three low-ABUK patents. *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, No. 11-cv-2037 (S.D.N.Y. Mar. 23, 2011), Dkt. No. 1.

Then, on June 28, 2012, Purdue and Grünenthal filed suit against Teva alleging infringement of the 383 abuse-deterrent patent. *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, No. 12-cv-5083 (S.D.N.Y. June 28, 2012), Dkt. No. 1.

The district court combined these cases for trial in the Fall of 2013 (the “Teva” action). *See, e.g., Purdue*, No. 12-cv-5083 (S.D.N.Y. Aug. 9, 2013), Dkt. No. 26.

D. The District Court Trial

The U.S. District Court for the Southern District of New York (Stein, J.), held a bench trial in the *Teva* action beginning on September 23, 2013.

Between September 23, 2013 and October 8, 2013, Purdue's attorneys (from Ropes & Gray, LLP) and Grünenthal's attorneys (from Finnegan, Henderson, Farabow, Garrett & Dunner LLP ("Finnegan")) represented Plaintiffs-Appellants on evidence and arguments relating to the abuse-deterrent patents. Carlson, Caspers, Vandenburg, Lindquist & Schuman, P.A. ("Carlson Caspers") represented Defendant-Appellee Teva in defending against those claims.

Starting on October 8, 2013, Purdue's attorneys (from Ropes & Gray, LLP) presented evidence and arguments relating to the low ABUK patents. During that phase of the trial, attorneys from Akin Gump defended Teva. There was no overlap in either fact or expert witnesses, nor in Teva's defense counsel between the abuse-deterrent and the low-ABUK phases of the trial.

The parties submitted post-trial briefs and on January 14, 2014, the district court issued its Findings of Fact and Conclusions of Law. *See Purdue*, No. 12-cv-5083 (S.D.N.Y. Jan. 14, 2014), Dkt. No. 45. The court found the challenged claims of the low-ABUK patents invalid because they would have been obvious. The court also found the challenged claims of the 383 patent invalid as anticipated

or because they would have been obvious. Accordingly, the district court entered judgment in favor of Teva (the “*Teva*” judgment) on all four patents.

E. Purdue’s and Grünenthal’s Case against Amneal

At the time of the *Teva* judgment, Purdue and Grünenthal were co-plaintiffs in related actions for patent infringement pending against multiple defendants in the Southern District of New York. *See Purdue Pharma L.P. et al. v. Amneal Pharms., LLC.*, No. 11-cv-8153 (S.D.N.Y.) (the “*Amneal*” action); *Purdue Pharma L.P. et al. v. Mylan Pharms., Inc. et al.*, No. 12-cv-2959 (S.D.N.Y.) (the “*Mylan*” action); *Purdue Pharma L.P. et al v. Epic Pharma, LLC*, No. 13-cv-683 (S.D.N.Y.) (the “*Epic*” action).

In the Amneal action, attorneys from Akin Gump are counsel defending Amneal against the Purdue low-ABUK patents. Although Grünenthal has not sued Amneal under Grünenthal’s abuse-deterrent patent at issue in this appeal, Amneal is represented by attorneys from Budd Larner, PC in Amneal’s defense against other related abuse-deterrent patents.

After the decision in the *Teva* action, on January 14, 2014, the district court issued an order for Purdue to show cause why those related actions should not be dismissed due to the collateral estoppel effect of the *Teva* judgment. On January 29, 2014, after considering Purdue’s response, the District Court entered judgment dismissing the *Amneal*, *Mylan*, and *Epic* actions based on collateral estoppel of the

Teva action. *See, e.g., Purdue Pharma L.P. v. Amneal Pharms., LLC*, No. 11-cv-8153 (S.D.N.Y. Jan. 29, 2014) (Order Dismissing Case), Dkt. No. 86.

Purdue and Grünenthal appealed the relevant judgments in those cases; those cases have been consolidated with the *Teva* action in this appeal.

F. Purdue's and Grünenthal's Appeal

On October 6, 2014, Purdue and Grünenthal filed their opening briefs in this appeal. Grünenthal's opening brief was 11,516 words and addressed only the 383 abuse-deterrent patent. In this appeal, Grünenthal is represented only by attorneys from Finnegan. But during trial, attorneys from both Finnegan and Ropes & Gray presented evidence on this patent.

On the same day that Grünenthal filed its opening appeal brief, Purdue filed its opening brief, which was 13,991 words and focused primarily on the low-ABUK patents, with a short section discussing the 383 patent. On appeal, Purdue is represented by attorneys from Ropes & Gray, and from Jones Day.

ARGUMENT

Each party to an appeal is generally entitled to file its own brief. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 n.3 (Fed. Cir. 2009) (considering separate response briefs filed by co-appellee's who each had separate counsel). But the difficulty for Appellees in this case arises from the Practice Note to Federal Circuit Rule 28, which states that:

When there are multiple parties represented by the same counsel or counsel from the same firm, a combined brief must be filed on behalf of all the parties represented by that counsel or firm.

Teva is represented by one law firm that is handling litigation over the abuse deterrent patents – Carlson Caspers. In this consolidated appeal, Mark D. Schuman from Carlson Caspers is designated as lead attorney for Teva.

Amneal has not been sued under the Grünenthal patent at issue on appeal. In litigation over related Grünenthal patents, Amneal has been represented by attorneys from Budd Larner, PC.

With respect to claims concerning the low-ABUK patents, however, Teva and Amneal are jointly represented by attorneys from Akin Gump. In this consolidated appeal, Barbara L. Mullin from Akin Gump is designated as lead attorney for Amneal and as counsel for Teva. But for this overlap in counsel for a subset of patents at issue on appeal, Amneal and Teva would each be free to file their own briefs.

Teva and Amneal agree with Appellants' approach of separating the two patent families into two largely independent briefs for the Court's consideration. Based on the discrete division of issues among counsel from different law firms at trial and in Appellants' opening briefs, the fact that Grünenthal has not asserted its 383 Patent against Amneal, and the designation of lead attorneys from different

law firms on appeal, Teva and Amneal respectfully submit that they should each be permitted to file their own brief. Separate briefs would allow Teva and Amneal to address arguments relating to the two patent families in a similar manner as Purdue and Grünenthal have organized the issues in their separate opening briefs.¹

In the alternative, Teva and Amneal respectfully request an extension of their response brief by 50%, from a limit of 14,000 words to a limit of 21,000 words, if needed.

At trial, Purdue and Grünenthal shared counsel for the purposes of trying the case (attorneys from Ropes & Gray did the bulk of the trial work for both patent families), but maintained their separate appearances on appeal, thus gaining the advantage of being able to file two separate briefs. Appellees did not share counsel in defending against these separate patent families at trial and should be permitted to respond accordingly and separately.

Accordingly, Teva and Amneal respectfully move this Court for permission to each file a response brief. One brief, by Teva, would respond to the opening brief filed by Appellant Grünenthal. The second brief, by Amneal, would respond to the opening brief filed by Purdue. If separate briefs are not permitted, then Teva

¹ Due to the particular facts of this case, Teva and Amneal foresee requesting a divided oral argument to aid resolution of issues related to the distinct patent families.

and Amneal respectfully move to expand the length of a single response brief to a limit of 21,000 words.

Dated: November 3, 2014

Respectfully submitted,

s/Mark D. Schuman

/s/ Barbara L. Mullin

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system. A copy of the foregoing was served via the CM/ECF system on all counsel of record.

Dated: November 3, 2014

/s/ Jason Weil
Jason Weil